DETAILED ACTION

Applicant's arguments, filed 01/20/2011, have been fully considered.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Applicant has cancelled claims 1-90, 93-104, 106-211, and 213-307.

Claims 91-92, 105, 212 are pending and under consideration.

Priority

Response to Arguments

Applicant's arguments, filed 01/20/2011, have been fully considered.

In response to applicant's arguments on pages 5-7 that the instant application should be granted priority to provisional application 60/076102, this application does NOT provide support for a chromosomal segment with a segment-subrange that is greater than or equal to the length of the human chromosome number 21, wherein the subrange of the segment-subrange includes at least a least common allele frequency of 0.1, as recited in claim 91.

However, after further consideration, PCT/US99/04376 DOES provide support for this limitation; therefore the instant application is granted the benefit of priority to PCT/US99/04376, filed FEBRUARY 26, 1999.

Claim Rejections - 35 USC § 112 1st Paragraph

Response to Arguments

Applicant's arguments, filed 01/20/2011, have been fully considered but are not persuasive for the following reasons.

In response to applicant's argument on page 11 that the facts of Fiers are NOT different from the instant claims because they "deal generally with DNA molecules", the instant claims require compositions comprising sets of DNA that are complementary to covering markers with very specific CL-R region limitations that are not contemplated by the Fiers case. Therefore this rejection is maintained for the following reasons.

In response to applicant's argument on pages 13-14 that the claimed invention meets the written description requirement since the claimed "product-by-process" invention can be distinguished from other materials, and because the claims have been simplified, it is the examiner's position that the specification does not provide any evidence that applicant was actually in possession of the claimed set of oligonucleotide compositions, as discussed below. Therefore it is unclear how these materials could be distinguished from other materials.

In response to applicant's argument on pages 14-15 that the claimed invention meets the written description requirement in view of Amgen, this case also has an entirely different fact pattern from those of the instant claims.

For these reasons, the rejection is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 91, 92, 105, and 212 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to a set of oligonucleotides, being complementary to a set of covering markers chosen so that a CL-F region is N-covered to within specific [x,y] two-dimensional distances and wherein the CL-F region that is N-covered to within [x,y], wherein x is less than or equal to 1 million base pairs and y is less than or equal to 0.2, ..., and wherein the length of the segment of the segment-subrange that is greater than or equal to the length of the human chromosome 21, wherein the subrange of the segment-subrange includes at least a least common allele frequency of 0.1, as in claim 91.

A review of the entire specification shows nothing more than a general discussion of conventional techniques for choosing a set of markers for scanning chromosomal regions; see e.g. pages 4 and 5. The specification also generally describes principles and concepts for using a set of oligonucleotides, technology for genotyping of individuals, and theoretical linkage studies and power analysis for bi-

allelic covering markers; see e.g. pages 22-22, 32, 35, 36, 37, and 39. However, the specification does not provide any evidence that applicant was actually in possession of the claimed set of oligonucleotide compositions (e.g. a disclosure of specific SEQ ID numbers) selected for a utility to determine genotype information as in claim 91. Therefore one of ordinary skill in the art would have reasonable doubt that the applicant was actually in possession of such oligonucleotide compositions obtained in the way the instant claims describe at the time the application was filed.

Claim rejections - 35 USC § 112, 2nd Paragraph

Response to Arguments

Applicant's arguments, filed 01/20/2011, have been fully considered but are not persuasive for the following reasons.

In response to applicant's statement on page 9 that the claims are directed to product by process, which are acts of the RCE, the claims are directed to a composition for use in obtaining genotype data, which is an intended use and is not a product by process claim because the claims do not recite any active limitations having to do with how the claimed composition is made. See MPEP 2173.05(p). Therefore it remains unclear what functional or structural limitations of the claimed composition are intended by the "wherein" phrases, as claimed.

Therefore the rejection is maintained for the reasons below.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

> The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Claims 91-92, 105, and 212 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims that depend directly or indirectly from claim 91 are also rejected due to said dependency.

Regarding claim 91: The claim is directed to a composition. However, the claim recites "wherein" phrases such as "wherein the set of oligonucleotides is selected for the set's utility to determine genotype data; and "wherein the group of covering markers is chosen so that....is N covered to within [x,y]; see at least claim 91, lines 4-9. These limitations appear to be method steps (e.g. selecting oligonucleotides and choosing covering markers). Therefore, as the claimed invention is directed to a composition of oligonucleotides, and is NOT directed to the "covering markers," it is unclear whether applicant intends these "wherein" phrases to be further limitations of the **claimed** composition and if so, what structural limitations of the claimed composition are intended in each case. Clarification is requested.

Regarding claims 92 and 105: These claims recite limitations of the CL-F region, covering markers, and allele frequencies. However, as the claimed invention is directed to a composition of oligonucleotides, it is unclear what structural limitations of the

claimed composition are intended by further limitations of the CL-F region, covering markers, and allele frequencies.

Regarding claim 212: The claim recites a utility to obtain genotype data or sample allele frequency data by generating a signal, wherein the signal is generated by the products of a polymerase chain reaction when oligonucleotides of the composition hybridize with one or more complementary alleles of one or more of the covering markers. These limitations appear to be intended use limitations and method steps (e.g. generating signals). It is unclear whether applicant intends these limitations to be further limitations of said composition and if so, what structural limitations of the claimed composition are intended.

Claim Rejections - 35 USC § 103

Response to Arguments

Applicant's arguments, filed 01/20/2011, have been fully considered and are persuasive. This rejection is withdrawn in view of change in the priority date of this application, as set forth above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached between 11am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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